

## Remarks

### Amendments to the Claims

The amendments to the claims do not add new matter. New claims 145-151 recite subject matter deleted from claims 1, 2, and 135-144. The recitation in claim 145 of an SPHK1-specific probe is supported *inter alia* on page 73, line 17 to page 77, line 12, which teaches various methods for detecting SPHK1 gene amplification using SPHK1-specific probes.

### Rejections Under 35 U.S.C. § 112 ¶ 1

Claims 1, 2 and 135-144 are rejected under 35 U.S.C. § 112 ¶ 1 as failing to comply with the written description requirement and as not being enabled. Applicants respectfully traverse these rejections.

Both rejections are based on the alleged breadth of the recited SPHK1 gene. On page 9, the Office Action contends that M.P.E.P. § 2111 requires that the Examiner “must consider the very broad definition of SPHK1 as provided by the Applicants’ [sic] themselves in constructing the breadth of the claimed methods.” This is not what the law or the cited portion of the M.P.E.P. requires. The cited portion states (emphasis added):

The [PTO] determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest **reasonable** construction “**in light of the specification as it would be interpreted by one of ordinary skill in the art.**” *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 [70 USPQ2d 1827] (Fed. Cir. 2004).

Construction of the claims must be guided by what would be considered reasonable by one of ordinary skill in the art. The Examiner has not explained why the ordinary artisan would consider it reasonable to construe the recited human SPHK1 gene, naturally present in human

tissues, to encompass such “a wide variety of nucleic acid sequences” that the claims lack written description and enablement.

Please withdraw the rejection.

#### Rejection Under 35 U.S.C. § 102(b)

Claims 1 and 2 stand rejected under 35 U.S.C. § 102(b) as anticipated by Michelland.<sup>1</sup> To advance prosecution, claims 1 and 2 have been amended to delete the recitation of lung cancer, as suggested in the Office Action. Lung cancer is now recited in new claims 145-151. These claims also recite use of an SPHK1-specific probe, which Michelland does not teach.

Michelland does not teach each element of claims 1 and 2 or each element of new claims 145-151. Please withdraw the rejection.

#### Rejections Under 35 U.S.C. § 103(a)

Claims 135-138 remain under 35 U.S.C. § 103(a) as obvious over Michelland. Claims 139-144 are rejected as obvious over Michelland in view of Meledez (Blast 2 Sequences results). Applicants respectfully traverse the rejections.

As explained above in connection with the rejection under 35 U.S.C. § 102(b), Michelland does not teach a method of screening for a breast, bladder, or colon cancer in a human comprising determining sphingosine kinase 1 SPHK1 human gene copy number, as recited in claims 1 and 2. Thus, Michelland does not teach or suggest each element of dependent claims 135-138. Nor does Michelland – even with the addition of the sequence disclosed by

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<sup>1</sup> Michelland *et al.*, *Cancer Genet. Cytogenet.* 114, 22-30, 1999.

Meledez – teach or suggest each element of dependent claims 139-144. Thus, there is no *prima facie* case that any of these claims is obvious over the references cited.

Please withdraw the rejection.

Respectfully submitted,  
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